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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,589	03/09/2001	Sean A. McCarthy	07334-325001 / MPI2000-54	6829

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,589	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *8-11,13-27 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* ~~are~~ was subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-37 are pending in the instant application.

Election/Restrictions

2. Applicant's election without traverse of Group 3, claims 1-7, 12 and 28 in Paper No. 8 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-11, 13-27 and 29-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-7, 12 and 28 are currently under examination.

Information Disclosure Statement

3. The PTO-1449 filed January 16, 2002 is present in the file. However, the references are not with the file and have not been found in the IDS storage facility. Therefore it is requested that Applicants submit a copy of the references for consideration with their response to this Office Action.

Priority Statement in Specification

4. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent applications. Applications 09/128,709 and 09/388,279 are abandoned, and Application 09/130,491 has issued as US Patent No. 6,416,974. This updated information should be included in the Cross References to Related Applications on the first page of the specification.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6.1 Claims 1, 2 and 12 are objected to because of the following informalities: they encompass non-elected inventions which should be deleted.

6.2 Claim 28 is also objected to for reciting "wherein the isolated nucleic acid comprises **a portion** having the nucleotide sequence", and the term "a portion" is awkward language in the context of the sentence.

Appropriate correction is required.

Drawings

7. Figures 1, 3, 5 and 7-9 of the instant application are presented on separate panels. 37 C.F.R. § 1.84(U)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, they must be identified by the same number followed by a capital letter, which has been done in the figures. However, the Brief Description of the Drawings do not reflect this. Applicant is required to file an amendment under 37 C.F.R. § 1.312 to change the Brief Description of the Drawings and the rest of the specification accordingly. For example, Figure 1 is divided into Figures 1A and 1B, and the Brief Description and all references to this figure in the specification must therefore refer to Figures 1A and/or 1B.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-7, 12 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claims 1-7, 12 and 28 are directed to isolated nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 5, or nucleic acid molecules which encode the amino acid sequence shown in SEQ ID NO: 6, which is identified as human TANGO-81. However, there is no specific use attributed to the nucleic acids and no specific activity attributed to the protein, and no disclosure of any protein or molecule (such as a receptor) that interacts with it. Therefore, the nucleic acids and encoded protein do not have any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant application teaches that the nucleic acid molecules of the invention can be used to recombinantly produce protein, to produce transgenic or knock-out animals, to detect nucleic acids (for example, to screen DNA libraries for orthologs or allelic variants), for genetic and chromosome mapping, tissue typing and forensic biology, for examples. The specification also teaches that the protein can be used to generate antibodies, or to screen for antagonists or agonists, screen for receptors (or other molecules) that bind to the polypeptide, and that the polypeptides of the invention have a biological or functional activity such as enzymatic activity or cellular signaling activity or ability to bind to an intracellular target, or have activites such as modulation of protein-protein interactions, development, differentiation, maturation,

proliferation and/or activity of cells function, survival and morphology, for example, and that antibodies directed against the protein can be used to detect protein expression in cells or tissues. However, either these uses are considered to be general uses or methods that would also apply to any nucleic acid or encoded protein (or antibody), and are not specific to the nucleic acids or protein of the instant invention, or the asserted uses (activities) have no support in the specification (enzymatic activity, signal transduction activity or cell proliferation activity, for examples).

The specification teaches that Tango 81 was isolated from a human fetal brain library, and that Northern blots demonstrate that Tango 81 is expressed in heart, brain, spleen, liver, lung, skeletal muscle, kidneys and testis (page 14), and that the nucleic acids, encoded protein or antibodies to protein can be used diagnostically (for example, to determine if nucleic acids or protein are inappropriately expressed, or to detect gene mutations) or therapeutically. Since Tango 81 is expressed in the brain, the specification asserts that Tango 81 polypeptides, nucleic acids and modulators thereof can be used to treat disorders of the brain such as cerebral edema, hydrocephalus, tumors, brain trauma, among other disorders or diseases listed on page 66. Similarly, based on tissue expression, the specification asserts that the Tango 81 and associated molecules can be used to treat cardiovascular diseases, disorders of the spleen and lung (page 67), liver and kidney disorders (page 68-69), reproductive disorders (pages 69-70), skeletal disorders (pages 70-71) and proliferative or inflammatory disorders (page 71). However, no correlation has been made between the Tango 81 gene and any disease or disorder, so that a diagnostic or therapeutic used is not a specific and substantial utility. There is no nexus between any of the disorders and the molecules of the instant invention. A stated belief that a correlation

exists between the nucleic acids (polypeptides) and the above diseases and disorders, based on tissue expression alone, is not sufficient guidance to use the claimed polynucleotides or proteins to treat and/or diagnose a particular disease; it merely defines a starting point for further research and experimentation. The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids.

In Brenner v. Manson, 148 U.S.P.Q. 689 (sus. Ct., 1966), the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad definition was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to polynucleotides encoding proteins which have undetermined function or biological significance, and the use of a protein to discover its properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be at least one specific and substantial activity or function known. It is possible that, after further characterization, the Tango 81 nucleic acid molecules or protein might be found to be associated with a specific disease, or the protein may be found to have a specific and substantial utility, in which case the nucleic acids would have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken the Applicant's claimed invention is incomplete. Because there is no specific and substantial utility asserted, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9.1 Claims 1-7, 12 and 28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of how to use the Tango 81 nucleic acid or polypeptide, enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the nucleic acids or proteins the skilled artisan would clearly not know how to use nucleic acids that encodes polypeptides that are 90% identical to the amino acid sequence of SEQ ID NO: 6, or polynucleotides encoding polypeptides comprising fragments of the amino acid sequence of SEQ ID NO: 6.

9.2 Claims 1, 3-7 and 12 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a nucleic acid molecule, SEQ ID NO: 5, encoding a polypeptide sequence consisting of SEQ ID NO: 6. However, the claims as written include nucleic acid molecules comprising small fragments of SEQ ID NO: 5 or encoding polypeptides comprising fragments and homologues or allelic variants, and encompass polypeptides that vary substantially in length and also in amino acid composition.

The instant disclosure of a single polypeptide, that of SEQ ID NO: 6, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated

polypeptide sequence SEQ ID NO: 6, with no disclosed activity, so there is no way to determine if any of the claimed variants would have the same or similar activity. Protein function cannot be reliably predicted from protein sequence homology, even between closely related proteins. For example, Transforming Growth Factor (TGF-beta) Family OP-1 induces metanephrongenesis whereas closely related TGF-beta family members-BMP-2 and TGF-beta1-have no effect on metanephrogenesis under identical conditions (Vukicevic et al., 1996, PNAS USA 93:9021-9026). Platelet-derived Growth Factor (PDGF) Family VEGF, a member of the PDGF family, is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells while PDGF is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (Tischer et al., U.S. Patent 5,194,596, column 2, line 46 to column 3, line 2). Finally, vertebrate growth hormone of 198 amino acids becomes an antagonist (inhibitor of growth) when a single amino acid is changed (Kopchick et al, U.S. Patent No. 5,350,836). Even 99% homology does allow predictability in this instance. Given the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. The instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7, 12 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10.1 Claims 1-7, 12 and 28 are indefinite because claims 1 and 12 encompass a nucleic acid molecule which hybridizes under "**stringent**" conditions. Though the specification on pages 17-18 describes various hybridization and wash conditions, they are exemplary. The term "**stringent**" is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The other claims are rejected for depending from claim 1.

10.2 Claim 12 is indefinite because in part (c), it encompasses "a complement thereof" of a polypeptide, and a complement of a polypeptide is not an art accepted term, whereas a complement of a nucleic acid encoding a polypeptide is.

Priority

35 U.S.C. § 120 states that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 119(e) states that:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

11. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 or § 119(e) from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, which respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a continuation of application Serial Numbers 09/128,709, 09/130,491, 09/388,280, 09/388,279, 60/054,645, 60/054,966 and 60/058,108, the prior applications do not meet those requirements and, therefore, are unavailable under 35 U.S.C. § 120 or § 119(e). The effective priority date of the instant application is considered to be the filing date of this application, March 30, 2001, because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12.1 Claims 1-7, 12 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fricker et al., The Journal of Neuroscience, 20(2):639-648, January 15, 2000.

Claims 1-7, 12 and 28 encompass an isolated nucleic acid molecule at least 90% identical to the nucleotide sequence of SEQ ID NO: 5 or encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 6, non- human mammalian host cell, vector comprising nucleic acid sequences encoding a heterologous polypeptide, and method of making polypeptide recombinantly. Fricker et al. disclose a nucleic acid sequence that is 96% identical to the nucleic acid sequence of SEQ ID NO: 5 of the instant application and 99.6% identical to the open reading frame (nucleotides 58-840 of SEQ ID NO: 5) and encodes a protein that is 100% identical to the polypeptide of SEQ ID NO: 6 of the instant application (see Figure 1 and attached sequence alignments). Fricker et al. also teach vectors comprising nucleic acid sequences encoding a heterologous polypeptide (pBluescript SK- and pcDNA3 vectors encoding selectable markers), non-human mammalian host cell (AtT-20 cells) and recombinant production of the protein (pages 640, 641, 643). Therefore, Fricker et al. anticipates the claims.

12.2 Claims 1-7, 12 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by McCarthy, WO 99/06427, February 11, 1999.

The claims are described above. McCarthy disclose a nucleic acid molecule (Figure 3, SEQ ID NO: 5) that is 100% identical to the nucleic acid molecule of SEQ ID NO: 5 of the instant application and that encodes a polypeptide that is 100% identical to the polypeptide of SEQ ID NO: 6 of the instant application (see attached sequence alignments). McCarthy also teaches vectors comprising nucleic acid sequences encoding a heterologous polypeptide, non-human

mammalian host cells and recombinant production of the protein (claims 1-7 and 12). Therefore, McCarthy anticipates the claims.

12.3 Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Database GenEmbl, Accession No. AF196971, November 9, 1999.

Claims 1 and 3-5 encompass an isolated nucleic acid molecule comprising at least 15 nucleotide residues having a nucleotide sequence identical to at least 15 consecutive nucleotide residues of SEQ ID NO: 5 or encoding a fragment of a polypeptide comprising at least 10 consecutive amino acids of SEQ ID NO: 6, vector comprising nucleic acid sequences encoding a heterologous polypeptide and host cell.

GenEmbl Accession No. AF196971 discloses a nucleic acid molecule that is 100% identical to nucleotides 170-429 (260 nucleotides) of SEQ ID NO: 5 of the instant application (see attached sequence alignment). Because the sequence has been cloned, it is by necessity in a vector further comprising a heterologous polypeptide (selectable marker) and host cell. This sequence encodes a polypeptide that is more than 10 consecutive amino acids of SEQ ID NO: 6. Therefore, GenEmbl Accession No. AF196971 anticipates the claims.

12.4 Claims 1, 3-7, 12 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruben et al., WO 00/04140, January 27, 2000.

Claims 1, 3-7, 12 and 28 encompass an isolated nucleic acid molecule at least 90% identical to the nucleotide sequence of SEQ ID NO: 5 or encoding a fragment of a polypeptide comprising at least 10 consecutive amino acids of SEQ ID NO: 6, vector comprising nucleic acid sequences encoding a heterologous polypeptide and non-human host cell, and method of making polypeptide recombinantly.

Ruben et al. disclose a nucleic acid sequence that is 93.2% identical to the nucleic acid sequence of SEQ ID NO: 5 of the instant application and encodes an amino acid fragment that is 100% identical to amino acids 1-51 of the polypeptide of SEQ ID NO: 6 of the instant application (see SEQ ID NOS: 58 and 238 and attached sequence alignments). Ruben et al. also teach vectors comprising nucleic acid sequences encoding a heterologous polypeptide, non-human mammalian host cell and recombinant production of the protein (pages 204-207). Therefore, Ruben et al. anticipates the claims.

12.5 Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mishra, US Patent No. 5,955,594, Sept. 21, 1999.

Claims 1 and 3-5 encompass an isolated nucleic acid molecule comprising at least 15 nucleotide residues having a nucleotide sequence identical to at least 15 consecutive nucleotide residues of SEQ ID NO: 5, vector comprising nucleic acid sequences encoding a heterologous polypeptide and non-human mammalian host cell.

Mishra discloses a nucleic acid molecule comprising a nucleotide sequence (SEQ ID NO: 18) that is identical to nucleotides 1-19 of SEQ ID NO: 5 of the instant application. Mishra also teaches cDNA libraries (vector encoding a heterologous polypeptide and host cell, Table 2, for example). Because the sequence has been cloned, it is by necessity in a vector further comprising a heterologous polypeptide (selectable marker) and host cell. Therefore, Mishra anticipates the claims.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Eileen B. O'Hara

Patent Examiner